REMARKS

The Office Action dated June 10, 2003 has been received, its contents carefully noted, and the applied citations thoroughly studied. Accordingly, the foregoing revisions to the claims are tendered with the conviction that patentable contrast has now been made manifest over the known prior art. Accordingly, all rejections tendered by the Examiner in the above-referenced Office Action are hereby respectfully traversed and reconsideration is respectfully requested.

It is believed that the foregoing revisions to the claims are within the metes and bounds of the recently articulated Supreme Court *Festo* case, in that all equivalents susceptible to capture have been retained in that one skilled in the art, at the time of this amendment, could not have reasonably be expected to have drafted a claim that would have literally encompassed any other equivalent.

Rejections under 35 U.S.C. §101

The Examiner has rejected claim 9 under 35 U.S.C.§ 101 because it is his opinion that the claimed invention is directed to nonstatutory subject matter, further suggesting the inclusion of "isolated" or "purified". Claim 9 has been amended to recite that the autologous thrombin is "isolated".

Rejections under 35 U.S.C. §112

The Examiner has rejected claim 9 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out distinctly claim the subject matter which applicant regards as the invention, referring specifically to the phrase "which provides fast clotting of less than five seconds which is stable for more than

15 minutes". Claim 9 has been amended hereinabove to make the reference more clear.

Rejections under 35 U.S.C. §102

The Examiner has rejected claim 10 under 35 U.S.C. §103(b) as being anticipated by Regan et al. (USP 5,674,482).

Regan et al. teaches a class of compounds and the determination of various properties of those compounds. The section to which the Examiner refers is the procedure for fractionating a crude product using a gel permeation chromatography column (col. 25, lines 40-41). The column is equilibrated using 50% aqueous ethanol, and 300mg of the sample is placed in 1-2 mL 50% aqueous ethanol and adjusted to pH 7.2 with sodium hydroxide (col. 25, lines 47-50). After the solution goes through the column to fractionate the sample, "the fractions are separately concentrated in vacuo" (col. 25, line 54). During this concentration step, the solvent is evaporated under vacuum to leave only the fraction of interest. Thus, there is no ethanol in the finished product, which is weighed: the ethanol has evaporated. The product on which APTT is performed contains no ethanol; therefore, no solution exists at any time that contains plasma, $CaCl_2$, and ethanol.

With respect to rejections under 35 U.S.C. § 102, the Examiner is invited to consider the following binding, compelling precedent articulated by the Court of Appeals for the Federal Circuit:

". . . anticipation requires that each and every element of the claimed invention be disclosed in a single prior art reference." *Akzo N.V. v. United States ITC*, 808 F.2d 1471, 1 U.S.P.Q.2d 1241 (Fed. Cir. 1986).

Further, "those elements must either be inherent or disclosed expressly . . ." *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 2 U.S.P.Q.2d 1051 (Fed. Cir. 1987). ". . . and must be arranged as in the claim[s] . . ." *Carella v. Starlight Archery & Pro Line Co.*, 804 F.2d 135, 231 U.S.P.Q. 644 (Fed. Cir. 1986).

In addition, ". . . [the] absence from the reference of any claimed element negates anticipation." *Kloster Speedsteel AB v. Crucible Inc.*, 793 F.2d 1565, 230 U.S.P.Q. 81 (Fed. Cir. 1986).

Because no solution in Regan et al. contains all of the claimed elements, plasma, ethanol, and $CaCl_2$, it cannot possibly anticipate the present invention as claimed.

Rejections under 35 U.S.C. § 103

The Examiner has rejected claim 10 under 35 U.S.C. § 103(a) as being unpatentable over Reid et al. (USP 5,476,771) taken with Gustafesson et al. (USP 5,965,692).

Reid et al. teaches "a quantitative method for determining the plasma levels of thrombin-specific inhibitors". Human alpha-thrombin is diluted in buffer containing calcium chloride, and fibrinogen samples are diluted in buffer containing no calcium (col. 4, lines 20-27). The two solutions are incubated separately and then combined and incubated again (col. 4, lines 29-33).

Claim 10 explicitly states "A thrombin composition consisting essentially of: Plasma; Ethanol (ETOH); $CaCl_2$." (emphasis added). The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of

the claimed invention. *In re Herz*, 537 F.2d 549,551-52, 190 USPQ 461,463 (CCPA 1976) (emphasis in original); MPEP 2111.03. Reid et al. states that the fact that fibrinogen is added in excess is considered one "of the novel aspects of [Reid et al.]" (col. 10, lines 32-34). Addition of fibrinogen, which is one of the clotting and adhesive proteins referred to in the specification (see, e.g., page 3, line 8), is contrary to the existence of the composition claimed in claim 10. The addition of excess fibrinogen to this composition would destabilize the system, forming fibrin clots (see, e.g., page 3, lines 2-6). Thus, the presence of excess fibrinogen in the system materially affects the basic and novel characteristics of the claimed composition; the claimed invention cannot include it, by virtue of the language "consisting essentially of".

Gustafesson et al. teaches a class of thrombin inhibitor compounds. One of the assay methods involves administering the compound in a mixture of ethanol:Solutol™:water to rats, then collecting the rats' urine and analyzing it. The analysis involved mixing the urine with pooled human plasma, and adding human thrombin and buffer (composition unspecified) (column 12, lines 14-34). The sample collected from the rat urine would not have any ethanol in it; any ethanol would have been metabolized by the rat. Thus, Gustafesson et al. does not add any ethanol component when it is combined with other references.

Thus, the combination propounded by the Examiner cannot produce the claimed invention. Reid et al. does violence to the claimed invention and Gustafesson adds no claimed element to the combination. The rejection under 35 U.S.C. § 103 must be withdrawn.

It is Black Letter Law the Patent and Trademark Office's burden is to establish a prima facie case of obviousness. The Patent and Trademark Office has met its burden only when it fully describes: "1) What the reference discloses, teaches and suggests to one skilled in the art; 2) What the reference lacks in disclosing, teaching or suggesting vis-à-vis the claimed features; 3) What particular teaching or suggestion is being relied upon either via a reference itself or knowledge of person of ordinary skill in the art; 4) A statement explaining the proposed modification in order to establish the prima facie case of obviousness; and finally 5) the motivation behind the statement of obviousness which comes from three sources: a) teachings of the prior art; b) nature of the problem to be solved; or c) knowledge of persons of ordinary skill in the art", *see In re Rouffet* 47 USPQ2d 1453 (Fed. Cir. 1998).

Undersigned has read these patents carefully and has failed to uncover the basis by which the Examiner has combined these references to support an obviousness type rejection. Stated alternatively, there is no teaching within these citations which would warrant the combination of elements proposed by the Examiner and it is respectfully stipulated that applicant's structure would still not be obtained thereby. A specific teaching within one of the references suggesting the combination is required.

No teaching or suggestion is present in the patents referenced by the Examiner. This fact, coupled with the statements made hereinabove regarding the absence of the claimed elements in the referenced patents, is sufficient to compel withdrawal of the rejection under 35 U.S.C. § 103.

In view of the foregoing, it is respectfully requested that the Examiner pass this case to issue. If, upon further consideration, the Examiner believes further issues remain outstanding or new ones have been generated, undersigned respectfully requests that the Examiner call undersigned to expeditiously resolve same.

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Respectfully Submitted:

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